SEP 2 7 2000

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510(k) SUMMARY

[As required by 21 CFR 807.87(h)]

Identification of Submitter

Submitter:	William Skremsky CTI PET Systems, Inc. 810 Innovation Drive Knoxville, TN 37932
Telephone No:	(865) 218-2522
Fax No:	(865) 218-3000
Date of preparation:	June 30, 2000

Identification of the Product

Device Proprietary Name:	ECAT Software Version 7.2 and ECAT DICOM Workstation
Common Name:	Positron Emission Tomography (PET) Scanner
Classification Name:	Emission Computed Tomography System per 21 CFR 892.1200

Marketed Devices to Which Equivalence is Claimed

Device	Manufacturer	510(k) Number
ECAT PET Scanner System & Software V 7.1	CTI PET Systems (CPS)	K974256
E.CAM Computer	Siemens Medical Systems	K992731

Device Description

ECAT Software is responsible for acquisition, reconstruction, archiving, display, and processing of data acquired from ECAT positron emission tomography (PET) scanners. In addition, the ECAT Software controls the motions of the patient handling system, transmission sources, and septa associated with the ECAT scanner. The ECAT Software is used in conjunction with ECAT tomographs for the purpose of imaging and measuring various metabolic and physiological functions within the human body.

ECAT Software Version 7.2

The ECAT Software Version 7.2 consists of modifications to ECAT Version 7.1 software that was included in the 510(k) notification K974256 for which CPS was granted marketing clearance. A subsequent version V7.1.1 ECAT Software was released with several minor bug fixes and to fully implement several features originally described in 510(k) K974256, that were intended to be in the 7.1 version software.

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The ECAT V7.2 software implements a PET image reconstruction subsytem that will run on a microcomputer CPU using standard operating system and file services. ECAT V7.2 will provide an improvement of image quality produced by OSEM reconstruction while maintaining quantitative accuracy, uniformity, and resolution specifications for the ECAT PET system. ECAT V7.2 will also include the implementation of gated cardiac acquisition for the ECAT ART PET scanner that was indicated in 510(k) K940478 for the ECAT ART scanner. This feature was implemented in ECAT system software V7.1 for the ECAT EXACT and ECAT EXACT HR+ PET scanners (K974256).

ECAT DICOM Workstation
THE CPS ECAT DICOM Workstation will provide DICOM connectivity for ECAT PET systems. The ECAT DICOM Workstation will facilitate the network transfer of PET images, in addition to other modality images, between ECAT PET systems and other DICOM compliant systems while maintaining data integrity.

ECAT DICOM will support DICOM Media Storage functions including the import of objects from local archive media into the ECAT database, exporting objects from the ECAT database to local archive media, and creating a new File-set onto an unwritten local archive medium. ECAT DICOM will support the following imaging modalities: PET, Nuclear Medicine, CT, MR, and Angiography Imaging.

ECAT DICOM Query/Retrieve functions will include the query and retrieval of the following: studies stored on stand-alone high capacity DICOM archive machine, requests from other DICOM nodes and studies from other DICOM nodes.

ECAT DICOM will serve as a DICOM storage server and will support the import and export of the following imaging modalities: PET, Nuclear Medicine, CT, MR, and Angiography Imaging.

ECAT DICOM Print function will communicate with DICOM compatible printers and provide an image viewing tool.

Indications for Use
Siemens/CPS ECAT positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

ECAT Software is used in conjunction with ECAT tomographs for acquisition, reconstruction, archiving, display and the processing of data acquired from ECAT PET scanners. In addition, the ECAT software controls the motions of the patient handling system, transmission sources and septa associated with the ECAT scanner.

The CPS ECAT DICOM Workstation is intended as an optional subsystem to provide DICOM connectivity for ECAT PET systems. The ECAT DICOM Workstation will facilitate the network transfer of PET images, in addition to other modality images, between ECAT PET systems and other DICOM compliant systems while maintaining data integrity.

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Comparison with Predicate Devices

ECAT Software Version 7.2 is similar in design and function to the previous version 7.1 ECAT system software described in our premarket notification K974526. ECAT Software Version 7.2 consists of modifications to ECAT V7.1 software. The software changes include:

1) the implementation of a PET image reconstruction subsytem that will run on a microcomputer CPU using standard operating system and file services;
2) an improvement of image quality produced by OSEM reconstruction while maintaining quantitative accuracy, uniformity, and resolution specifications for the ECAT PET system;
3) the implementation of gated cardiac acquisition for the ECAT ART PET scanner and
4) minor bug fixes.

The ECAT DICOM Workstation which provides for DICOM connectivity for ECAT PET systems has technological characteristics similar to Siemens E.Soft DICOM which was submitted in the E.CAM Computer 510(k) notification, K992731. Similar to E.Soft, the ECAT DICOM Workstation will serve as a DICOM storage server and will support the import and export of the following imaging modalities: PET, Nuclear Medicine, CT, MR, and Angiography Imaging. ECAT DICOM will also support DICOM Media Storage and DICOM Query/Retrieval functions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 27 2000

William Skremsky
Regulatory Affairs Specialist
CTI, Inc.
810 Innovation Drive
Knoxville, TN 37932

Re: K002039
ECAT Software Version 7.2 and ECAT DICOM Workstation
Dated: June 30, 2000
Received: July 5, 2000
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Skremsky:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Acting Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

510(k) Number (if known): K002039

Device Name: ECAT Software Version 7.2 and ECAT DICOM Workstation

Indications for Use:

Siemens/CPS ECAT positron emission tomography (PET) scanners are intended to be utilized by appropriately trained health care professionals to image and measure the distribution of injected positron emitting radiopharmaceuticals in humans for the purpose of determining various metabolic and physiologic functions within the human body.

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The CPS ECAT DICOM Workstation is intended as an optional subsystem to provide DICOM connectivity for ECAT PET systems. The ECAT DICOM Workstation will facilitate the network transfer of PET images, in addition to other modality images, between ECAT PET systems and other DICOM compliant systems while maintaining data integrity.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

David A. Feigal

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K002039